Art Unit: 1648

Cpto

Amdt. Filed 01/09/02

CET (04.18.05)

Claims 1-18 (Cancelled)

- 19. (Amended) A process for inducing a neutralizing antibody response in a subject against a pathogenic organism resulting in neutralizing antibodies in one or more of vaginal secretions, intestinal secretions, respiratory secretions and feces, which process comprises administering to the subject an effective amount of a vaccine composition capable of éliciting neutralizing antibodies in a subject to a pathogenic organism which antibodies are present in vaginal secretions, intestinal secretions, respiratory secretions or feces, which composition comprises:
 - (a) a viral or bacterial antigen comprising a protein having
 - (i) an endogenous hydrophobic sequence of between about 3 and about 50 non-polar or uncharged amino acids;
 - (ii) added to the protein, an exogenous hydrophobic material comprising a sequence of between about 3 and about 50 non-polar or uncharged amino acids or a C8-C18 fatty acyl group; or
 - (iii) both (i) and (ii),
 - (b) complexed with said antigen, a composition comprising proteosomes, bioadhesive nanoemulsions, or both,

wherein said complexed or coupled protein maintains a native structure of antigenic epitopes such that, upon administration to said subject, the antigen induces neutralizing antibodies in one or more of vaginal secretions, intestinal secretions, respiratory secretions and feces, capable of neutralizing said pathogenic organism.

Art Unit: 1648

Ò

Claim 20 (Original)

- 20. A process according to claim 19 wherein the exogenous hydrophobic material of said vaccine composition is a C8-C18 fatty acyl group.
- 21. (Amended) A process according to claim 19 wherein the exogenous hydrophobic material of said vaccine composition is lauroyl, Phe Leu Leu Ala Val (SEQ ID NO:2) or Val Ala Leu Leu Phe (SEQ ID NO:3).

Claims 22-24 (Original)

- 22. A process according to claim 19 wherein the protein is a viral envelope protein.
 - 23. A process according to claim 22 wherein the viral envelope protein is an oligomeric gp160 from HIV-1.
 - 24. A process according to claim 23 wherein said oligomeric gp160 has the sequence of residues 33-681 of SEQ ID NO:1.

Claim 25 (Cancelled)

- 26. (Amended) A process according to claim 19 wherein the protein is recombinantly produced.
- 27. (Amended) A process according to claim 19, wherein said vaccine composition is formed by
 - (a) bonding the hydrophobic material to said protein to form a hydrophobic-hydrophilic compound; and
 - (b) admixing said compound with said proteosomes, bloadhesive nanoemulsions, or both such that said antigen is complexed with said proteosomes or nanoemulsion.

Art Unit: 1648

į,

Claims 28-29 (Original)

28.. A process according to claim 27 wherein said admixing step is performed in the presence of a detergent, and is followed by the step of

- (c) removing the detergent by dialysis.
- 29. A process according to claim 27 wherein said admixing step is performed lyophilization.
- 30. (Amended) A process for inducing a neutralizing antibody response in a subject against a pathogenic organism resulting in neutralizing antibodies in one or more of vaginal secretions, intestinal secretions, respiratory secretions and feces, which process comprises administering to said subject by intranasal or respiratory route a vaccine composition formulated for intranasal or respiratory administration and capable of eliciting neutralizing antibodies in a subject to a pathogenic organism which antibodies are present in vaginal secretions, intestinal secretions, respiratory secretions or feces, which composition comprises:
 - (a) a viral or bacterial antigen comprising a protein having
 - (i) an endogenous hydrophobic sequence of between about 3 and about 50 non-polar or uncharged amino acids;
 - (ii) added to the protein, an exogenous hydrophobic material comprising a sequence of between about 3 and about 50 non-polar or uncharged amino acids or a C8-C18 fatty acyl group; or
 - (iii) both (i) and (ii),
 - (b) complexed with said antigen, a composition comprising proteosomes, bioadhesive nanoemulsions, or both,

wherein said complexed or coupled protein maintains a native structure of antigenic epitopes such that, upon administration to said subject, the antigen induces neutralizing antibodies in one

or more of vaginal secretions, intestinal secretions, respiratory secretions and feces, capable of neutralizing said pathogenic organism.

Art Unit: 1648

Claims 31-31 (Original)

- 31. A process according to claim 19 wherein the pathogenic organism is a causative agent of a mucosally-transmitted or sexually transmitted disease.
- 32. A process according to claim 30, wherein the pathogenic organism is a causative agent of a mucosally transmitted or sexually transmitted disease.

j